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Re-evaluation Note REV2017-21

Re-evaluation Project Plan for Fenhexamid

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Background

In Canada, fenhexamid is under re-evaluation by Health Canada's Pest Management Regulatory Agency (PMRA). The PMRA re-evaluates registered pesticides to determine whether the use of these products continues to be acceptable in terms of value, human health and the environment according to current standards.

Fenhexamid is a fungicide registered for use on fruit crops, greenhouse vegetables, and greenhouse and outdoor ornamentals. As of 7 June 2017, there are one technical and two commercial class end-use products containing fenhexamid registered in Canada.

Under the authority of section 16 of the *Pest Control Products Act*, the registrant of fenhexamid was notified of the initiation of the re-evaluation of fenhexamid. Following this, the registrant of fenhexamid technical grade active ingredient in Canada indicated support of all uses included on the labels of end-use products in Canada.

The re-evaluation project plan below outlines the timeline, the anticipated areas of focus for the risk assessments, and the data requirements for the re-evaluation of fenhexamid.

Re-evaluation Project Plan

Anticipated Re-evaluation Timeline

The re-evaluation of fenhexamid is defined as a Category 1 as described in Regulatory Directive DIR2016-04, *Management of Pesticides Re-evaluation Policy*. However, because this re-evaluation was initiated prior to the publication of DIR2016-04, the proposed re-evaluation decision for fenhexamid is anticipated to be published for consultation by September 2019. The re-evaluation timeline may be updated if, during the risk assessment, the PMRA identifies additional areas of focus that should be considered.

Human Health Risk Assessment

New assessments will be conducted for toxicology, dietary exposure, occupational exposure and residential exposure.

Environmental Risk Assessment

New assessments will be conducted for environmental fate, water modelling and environmental exposure.

Value

The value of fenhexamid will be considered. The viability of alternatives will be examined for certain uses if risks of concern which require mitigation are identified.

Data Requirements

The PMRA has identified the need for the technical registrant to provide data for fenhexamid related to toxicology, occupational, residential and bystander exposure, dietary exposure, environmental chemistry and fate, and environmental toxicology. Relevant data/studies have been requested from the technical registrant. A summary of the data call-in is found in the PMRA's Public Registry, found online at https://www.canada.ca/en/health-canada/services/consumer-product-safety/pesticides-pest-management/public/protecting-your-health-environment/public-registry.html. For a list of data categories that have been required, see Appendix I. In addition, information regarding the registered use pattern has been requested from the registrant, to inform the risk assessments.

Additional Information

PMRA documents can be found in the Pesticides and Pest Management portion of the Canada.ca website at https://www.canada.ca/en/health-canada/services/consumer-product-safety/pesticides-pest-management.html. The PMRA documents are also available through the Pest Management Information Service:

Phone:	1-800-267-6315	within Canada, or
	1-613-736-3799	outside Canada (long distance charges apply)
Fax:	1-613-736-3798	
E-mail:	pmra.infoserv@hc-sc.gc.ca	

Appendix I Data Required Under Subsection 19(1) of the *Pest Control Products Act* for the Re-evaluation of Fenhexamid

I. Toxicology Data

DACO 4.2.6	Dermal Sensitization
DACO 4.3.1	Short-term Oral (90-day rodent)
DACO 4.3.7	Short-term Inhalation (21/28-day)
DACO 4.5.4	Genotoxicity: Bacterial Reverse Mutation Assay
DACO 4.5.8	Other Genotoxicity Studies
DACO 4.8	Other Studies/Data/Reports
DACO 12.7	Comprehensive Data Summaries (if available)

II. Occupational, Residential and Bystander Exposure Data

DACO 5.8	Dermal Absorption (in vivo)
DACO 5.9	Dislogeable Residues (Foliar, Soil and Surface)
DACO 12.7	Comprehensive Data Summaries (if available)

III. Dietary Exposure Data

DACO 7.4.1	Supervised Residue Trial Studies
DACO 12.7	Comprehensive Data Summaries (if available)

IV. Environmental Chemistry and Fate Data

DACO 8.2.3.4.2	Biotransformation in Soil - Aerobic Soil 20°-30°C
DACO 8.2.3.5.4	Biotransformation in Aquatic Systems - Aerobic Water/Sediment 20°-30°C
DACO 8.2.3.5.6	Biotransformation in Aquatic Systems - Anaerobic Sediment/Water 20°-30°C

V. Environmental Toxicology Data

DACO 9.2.4.3	Bee Larvae Toxicity
DACO 9.2.4.4	Bee Adult Chronic Toxicity
DACO 9.3.4	Non-Target Freshwater Invertebrates - Laboratory Studies with Other Species
DACO 9.4.2	Non-Target Marine Invertebrates - Acute (Crustacean)
DACO 9.4.5	Non-Target Marine Invertebrates - Chronic (Mollusk or Crustacean)
DACO 9.8.2	Non-Target Plants - Fresh Water Algae
DACO 9.8.3	Non-Target Plants - Marine Algae
DACO 9.8.4	Non-Target Plants - Terrestrial Vascular Plants
DACO 12.7.4	Comprehensive Data Summaries (if available)